

Office of the Secretary of Defense

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given to the proposed change by the department or agency.

§ 219.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ 219.121 [Reserved]

§ 219.122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ 219.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the ap-

plicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§ 219.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

PART 220—COLLECTION FROM THIRD PARTY PAYERS OF REASONABLE COSTS OF HEALTHCARE SERVICES

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AUTHORITY: 5 U.S.C. 301; 10 U.S.C. 1095.

SOURCE: 55 FR 21748, May 29, 1990, unless otherwise noted.

§ 220.1 Purpose and applicability.

This part implements the provisions of 10 U.S.C. 1095. In general, 10 U.S.C. 1095 establishes the statutory obligation of third party payers to reimburse the United States the reasonable costs of healthcare services provided by facilities of the Uniformed Services to most Uniformed Services medical care beneficiaries who are also covered by a

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third party payer's plan. This part establishes the Department of Defense interpretations and requirements applicable to all healthcare services subject to 10 U.S.C. 1095.

[57 FR 41100, Sept. 9, 1992]

§ 220.2 Statutory obligation of third party payer to pay.

(a) *Basic rule.* Pursuant to 10 U.S.C. 1095(a)(1), a third party payer has an obligation to pay the United States the reasonable costs of healthcare services provided in any facility of the Uniformed Services to a Uniformed Services beneficiary who is also a beneficiary under the third party payer's plan. The obligation to pay is to the extent that the beneficiary would be eligible to receive reimbursement or indemnification from the third party payer if the beneficiary were to incur the costs on the beneficiary's own behalf.

(b) *Application of cost shares.* If the third party payer's plan includes a requirement for a deductible or copayment by the beneficiary of the plan, then the amount the United States may collect from the third party payer is the reasonable cost of the care provided less the appropriate deductible or copayment amount.

(c) *Claim from United States exclusive.* The only way for a third party payer to satisfy its obligation under 10 U.S.C. 1095 is to pay the facility of the uniformed service or other authorized representative of the United States. Payment by a third party payer to the beneficiary does not satisfy 10 U.S.C. 1095.

(d) *Assignment of benefits not necessary.* The obligation of the third party payer to pay is not dependent upon the beneficiary executing an assignment of benefits to the United States.

[55 FR 21748, May 29, 1990, as amended at 57 FR 41101, Sept. 9, 1992]

§ 220.3 Exclusions impermissible.

(a) *Statutory requirement.* Under 10 U.S.C. 1095(b), no provision of any third party payer's plan having the effect of excluding from coverage or limiting payment for certain care if that care is provided in a facility of the uniformed

services shall operate to prevent collection by the United States.

(b) *General rules.* Based on the statutory requirement, the following are general rules for the administration of 10 U.S.C. 1095 and this part.

(1) Express exclusions or limitations in third party payer plans that are inconsistent with 10 U.S.C. 1095(b) are inoperative.

(2) No objection, precondition or limitation may be asserted that defeats the statutory purpose of collecting from third party payers.

(3) Third party payers may not treat claims arising from services provided in facilities of the uniformed services less favorably than they treat claims arising from services provided in other hospitals.

(4) No objection, precondition or limitation may be asserted that is contrary to the basic nature of facilities of the uniformed services.

(c) *Specific examples of impermissible exclusion.* The following are several specific examples of impermissible exclusions, limitations or preconditions. These examples are not all inclusive.

(1) *Care provided by a government entity.* A provision in a third party payer's plan that purports to disallow or limit payment for services provided by a government entity or paid for by a government program (or similar exclusion) is not a permissible ground for refusing or reducing third party payment.

(2) *No obligation to pay.* A provision in a third party payer's plan that purports to disallow or limit payment for services for which the patient has no obligation to pay (or similar exclusion) is not a permissible ground for refusing or reducing third party payment.

(3) *Exclusion of military beneficiaries.* No provision of an employer sponsored program or plan that purports to make ineligible for coverage individuals who are uniformed services health care beneficiaries shall be permissible.

(4) *No participation agreement.* The lack of a participation agreement or the absence of privity of contract between a third party payer and a facility of the uniformed services is not a permissible ground for refusing or reducing third party payment.

[55 FR 21748, May 29, 1990, as amended at 57 FR 41101, Sept. 9, 1992]